

Department of Veterans Affairs

§ 1.475

Health Service Act (42 U.S.C. 241(d) and the implementing regulations at 42 CFR Part 2a); or Sec. 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These “research privilege” statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* Sections 1.460 through 1.499 of this part restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under §§ 1.490 through 1.499 of this part of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilege granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with §§ 1.490 through 1.499 of this part authorizes a VA facility to disclose certain information about its patients, the facility may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

(Authority: 38 U.S.C. 7334)

§ 1.469 Patient access and restrictions on use.

(a) *Patient access not prohibited.* Sections 1.460 through 1.499 of this part do not prohibit a facility from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that VA maintains about the patient, subject to the provisions of the Privacy Act (5 U.S.C.

552a(d)(1)) and 38 CFR 1.577. If the patient is accompanied, giving access to the patient and the accompanying person will require a written consent by the patient which is provided in accordance with § 1.475 of this part.

(b) *Restrictions on use of information.* Information obtained by patient access to patient record is subject to the restriction on use of this information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 1.461(d)(1) of this part.

(Authority: 38 U.S.C. 7334)

§§ 1.470–1.474 [Reserved]

DISCLOSURES WITH PATIENT’S CONSENT

§ 1.475 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under §§ 1.460 through 1.499 of this part must include:

(1) The name of the facility permitted to make the disclosure (such a designation does not preclude the release of records from other VA health care facilities unless a restriction is stated on the consent).

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 1.464 of this part; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 1.465 of this part in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the facility which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.